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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,633

07/17/2007

Karl-Hermann Schmidt

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05/25/2010

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,633	<b>Applicant(s)</b> SCHMIDT ET AL.	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19,21-23 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19,21-23 and 26-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☒ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/22/09; 4/7/08; 9/5/06</u> .                                 | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. Applicant's election with traverse of Group I (claims 1-19, 21-23, 26-29) in the reply filed on March 04, 2010 is acknowledged. The traversal is on the ground(s) that examiner failed to show why the groups I and II lack of special technical feature.. The arguments are found unpersuasive because of the following reasons: (i) this application is a 371 of PCT/2007/017015 and for applications filed under 371, PCT rules for lack of unity apply and lack of unity is based on the X category reference which anticipates broad claim 1 (ii) search burden is not required to show lack of unity. (ii) as discussed in the previous office action, the US 5,817,290 anticipates the broad claim 1 and indicates claim 1 lacks special technical feature, which supports that each of the groups of invention do not relate to a single inventive concept. (iii) Further Applicants' arguments on lack of teaching of CPGB protein in said prior art ('290) have been found unpersuasive because the broad claim only requires 25 to 35% sequence similarity to said CPGB protein and the prior art does teach said protein. Thus the lack of unity is deemed proper.

***Status***

2. Claims 1-19, 21-23, 26-29 are considered for examination. Claims 24-25 are cancelled by the amendment filed on 3/4/10.

***Priority***

3. This application filed on July 17, 2007 is a 371 of PCT/EP05/02198 filed on 3/2/2005 which claims foreign priority to GERMANY 10 2004 010 928.1 filed on 3/05/2004 and GERMANY 10 2005 001 889.0 filed on 1/14/2005. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English

translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

***Information Disclosure Statement***

4. The Information Disclosure Statement filed on September, 05, 2006, April 07, 2008 and April 22, 2009 have been considered and acknowledged.

***Specification***

5. The specification is objected because of the following informalities:

(i) Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

the abstract contains 'said', which should be avoided.

(ii) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code (see page 4, line 19). See MPEP § 608.01.

(iii) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However,

this application fails to comply the requirements of 37 CFR 1.821 through 1.825. The instant application recites sequences that are not identified by SEQ ID No. (see at least page 16, line 19-20, page 17. line 4-5, Fig. 1-2) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.). Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 1, 4-6, 10, 12-19, 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Vijg et al. (US 5,817,290).

Vijg et al. teach a method of claim 1, 27, of separating and enriching prokaryotic DNA comprising

(a) contacting at least one prokaryotic DNA (plasmid DNA), present in a solution, with a protein (LacI repressor protein) which binds to prokaryotic DNA having 25 % homology with CPGB protein, thereby forming a protein-DNA complex (see col. 8, line 1-24);

(b) separating said complex (see col. 8, line 19-24).

With regard to claim 4, Vijg et al. teach that the separation is followed by separation of DNA from the protein of the complex (see col. 8, line 19-24).

With regard to claim 5-6, 10, 12, 14, Vijg et al. teach that the protein is bound directly to a carrier and the carrier is a microparticle or magnetic bead or an antibody or antiserum (see col. 8, line 19, col. 5, line 39-46).

With regard to claim 13, Vijg et al. teach that the separation is effected by means of electrophoresis (see col. 11, line 27-39, col. 19, line 6-21).

With regard to claim 15-16, Vijg et al. teach that the solution contains a mixture of prokaryotic and eukaryotic DNA and the prokaryotic DNA is bacterial DNA (see col. 8, line 2-5, col. 11, line 27-39).

With regard to claim 17, 26, Vijg et al. teach that the solution is derived from body fluid comprises cell preparation from blood (spleen) (see col. 15, line 15-26).

With regard to claim 18-19, Vijg et al. teach that the separation is achieved by means of a filter matrix upon which the protein is immobilized (see col. 19, line 6-21)

With regard to claim 28-29, Vijg et al. teach diagnosis of cancer having specific methylation pattern (see col. 9, line 54-65). Accordingly the claims are anticipated.

B. Claims 1-14, 21-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Bird et al. (US 2008/0076671A).

Bird et al. teach a method of claim 1, of separating and enriching prokaryotic DNA comprising

(a) contacting at least one prokaryotic DNA (plasmid DNA), present in a solution, with a protein (CpG binding protein) which binds to prokaryotic DNA having 25 % homology with

CPGB protein, thereby forming a protein-DNA complex (see page 2, paragraph 0016-0028, page 8, paragraph 0139, page 9, paragraph 0140-0147);

(b) separating said complex (see page 2, paragraph 0017-0018, page 9, paragraph 0148-150).

With regard to claim 2, Bird et al. teach that the protein comprises 25 to 35 % homology to SEQ ID NO. 2 as follows

```
AEH42862
ID  AEH42862 standard; peptide; 44 AA.
AC  AEH42862;
DT  29-JUN-2006 (first entry)
DE  CxxC- domain of CGBP.
KW  DNA methylation; DNA microarray; DNA library; CGBP.
OS  Unidentified.
PN  WO2006046076-A2.
PD  04-MAY-2006.
PF  31-OCT-2005; 2005WO-GB004202.
PR  29-OCT-2004; 2004GB-00023991.
PA  (UYED-) UNIV EDINBURGH.
PI  Bird AP, Illingworth RS, Jorgensen HF;
DR  WPI; 2006-332318/34.
SQ  Sequence 44 AA;

Query Match      26.9%; Score 262; DB 2; Length 44;
Best Local Similarity 100.0%;
Matches 44; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      60 SARMCGECEACRRTEDCGHCDFCRDMKKFGGPNKIRQKCRLRQC 103
      |||||
Db      1 SARMCGECEACRRTEDCGHCDFCRDMKKFGGPNKIRQKCRLRQC 44
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With regard to claim 3, Bird et al. teach that the protein is capable of recognizing non-methylatedCpG motifs (see page 2, paragraph 0028).

With regard to claim 4, Bird et al. teach that the separation is followed by separation of DNA from the protein of the complex (see page 3, paragraph 0049, page 9, paragraph 0148-150).

With regard to claim 5-12, 14, Bird et al. teach that the protein is bound directly or indirectly to a carrier by means of an antibody or a spacer or linker and the carrier is a sepharose (see page 2, paragraph 0019-0021, 0029-0036, page 3, paragraph 0037-0039).

With regard to claim 13, Bird et al. teach that the separation is effected by means of electrophoresis (see page 9-10, paragraph 0150).

With regard to claims 21-22, Bird et al. teach that the method further comprises amplification of prokaryotic DNA after separation step said method comprises separating DNA from the complex, denaturing the double stranded DNA, hybridizing primers generating amplified products with polymerase and repeating amplification steps up to the desired degree of amplification (see page 5, paragraph 0075-0080, 0082-0083).

With regard to claim 23, Bird et al. teach that the method further comprises cloning the DNA in to a vector, transforming suitable cells with the vector, cultivating the transformed cells, isolating the vectors and isolating the DNA (see page 3, paragraph 0050-0053, page 4, paragraph 0054). Accordingly the claims are anticipated.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/  
Primary Examiner, Art Unit 1637